II. REMARKS

A. Status of the Claims

Claims 1-16 and 18-85 were pending in the case at the time of the Action. Claims 1-18, 26-37, 42, and 66-77 have been canceled without prejudice or disclaimer. Claims 19, 22, 24, 38, 41, 43-45, 48, 52, 54-55, 57, 59, 62-63, 65, 78-81, and 84 have been amended in the Amendment set forth herein. No new claims have been added. Thus, claims 19-25, 38-41, 43-65, and 78-88 are currently under consideration.

Support for the amendments to the claims can be found generally throughout the specification, such as in the claims as originally filed. Written description support for the new and amended claims is discussed in greater detail in the specification below.

B. Interview with Examiner Ketter

On Thursday, April 13, 2006, Applicant's representatives, David Parker, Monica De La Paz, and Michael Samardzija, interviewed Examiner Ketter to discuss the final Office Action dated December 15, 2006. The Examiner was forwarded a draft set of amended claims for discussion during the teleconference. Each of the rejections set forth in the Office Action was addressed, and proposed claim amendments were discussed. The Examiner invited Applicant to submit Amendments in a formal response, and has indicated that the Amendments would be entered. These rejections are individually addressed as follows.

C. The Claim Rejections Under 35 U.S.C. §102(b) are Overcome

Claims 16, 18, 20, 22-24, 38, 40-43, 48, 49, 52, 53, 55-60, 65, 66, 78, 79, and 80 have been rejected under 35 U.S.C. §102(b) as being anticipated by Coward *et al.* (PNAS Vol. 95, January 1998 pp. 352-357). According to the Action, Coward is said to disclose a method comprising introducing a nucleic acid encoding a recombinant G-protein coupled receptor into a

cell and detecting expression of the G-protein coupled receptor based on a ligand's interaction with the receptor. Applicant respectfully traverses this rejection, and responds as follows.

Without conceding that the claims as originally written were anticipated by Coward *et al.*, Applicant points out that in view of the Amendment set forth herein, the rejection has been overcome. Claim 19, which was not rejected, has been amended to be an independent claim (claims 16 and 18 having been canceled). Claims 22, 41, 42, 44, 48, and 52 have been amended to depend from claim 19. Therefore, the rejection as to claim 19 and its dependent claims is moot. Regarding independent claim 55, it has been amended in the Amendment set forth herein to refer "recombinant SSTR" rather than "recombinant seven transmembrane G protein associated receptors." Coward appears to pertain to certain G-peptide coupled peptide receptors designed "RASSLs," and not to SSTR. See, e.g., abstract. Because Coward appears to provide express or inherent disclosure of recombinant SSTRs, this rejection has been overcome.

In view of the above, Applicant respectfully requests that the rejection under 35 U.S.C. §102(b) should be WITHDRAWN.

D. The Rejections Under 35 U.S.C. §112, First Paragraph, Are Overcome

Claims 16, 18-25, 36-65, and 78-85 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. According to the Action, the claims were not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In particular, the specification is said to not disclose a representative number of species of the broad genuses claimed to provide adequate written description. Applicant respectfully traverses, and respond as follows.

Applicant, without conceding that the claims as originally filed lacked adequate written description support in the specification, points out that both independent claims (*i.e.*, claims 19

and 55), recite "recombinant somatostatin receptor (SSTR)" rather than "recombinant seven transmembrane G-protein associated receptor." Support for "recombinant somatostatin receptor" (SSTR) can be found throughout the specification, such as in the claims as originally filed.

1. Applicant is Not Required to Recite Sequence Information Where the Sequences are Well-Known to Those of Ordinary Skill in the Art

SSTR sequences are well-known in the art. Applicant is not required to recite in the specification sequences that are known in the art where the claims are drawn to chimeric nucleic acid or amino acid sequences that are well-known in the art. In particular, in *Capon v. Echhar v. Dudas*, an interference proceeding, the Federal Circuit held that in claims directed to chimeric sequences, the Applicant is not necessarily required to recite the component nucleic acid sequences where those sequences are well-known to those of ordinary skill in the art. *Capon v. Eshhar v. Dudas*, 418 F.3d 1349, 1358 76 U.S.P.Q. 1078 (Fed. Cir. 2005). "When the prior art includes the nucleotide information, precedent does not set a *per se* rule that the information must be determined afresh." *Id.* Both parties state that a person experienced in the field of this invention would know that these known DNA sequences would retain their DNA sequences when linked by known methods." *Id.* Therefore, "[t]he Board erred in holding that the specifications do not meet the written description requirement because they do not reiterate the structure or formula or chemical name for the nucleotide sequences of the claimed chimeric genes." *Id.*

2. The Specification Recites Substantial Information Regarding SSTRs

The specification recites substantial information regarding SSTRs such that one of ordinary skill in the art would understand that the inventor had possession of the claimed invention. As set forth in the specification, the sequences of SSTRs are well-known in the art. In particular, "[g]ene sequences encoding human, rat, and, in some cases mouse somatostatin

receptor (SSTR) subtypes 1, 2, 2b, 3, 4, and 5 have been published in the literature." Citing Bruns *et al.*, Ann. NY Acad. Sci, 733, 138-146, 1994, and references cited therein. Further, accession numbers for exemplary mRNAs encoding these receptors can be found in para [0081] of the specification. Further, the specification provides detail regarding the cloning of SSTR2A. For example, information regarding the cloning of this sequence can be found in the Examples in paras [0058]-[0074] of the specification. Information regarding the structure and function of SSTR2A receptors is discussed in the specification. See, *e.g.*, para. [0065], citing Koenig, *et al.*, Biochem. J. 336:291-298 and Roth *et al.*, DNA and Cell Biology 16:111-119, 1997.

3. Claims 19 and 55 as Written Encompass Sequence Variants Such as Truncated Sequences

The claims as they currently read no longer recite "mutant somatostatin type 2 receptor." It appears from the Action that the Examiner, for whatever reason, found this language objectionable. Without conceding that the specification lacked written description support for "mutant somatostatin type 2 receptor," this language has been deleted from the claims.

Nevertheless, the claims as currently written are directed to recombinant somatostatin receptors, and encompassed within the term "recombinant somatostatin receptors" are variants of these receptors that may substantially alter its basic biological characteristics, for example ligand binding, antibody recognition and the like. Specification, para [0006]. Further, truncated variants are also contemplated. See, *e.g.*, specification, para [0060]. Further, dependent claims 42, and 43 recited truncated receptors, as did independent claim 55 prior to the present amendment. Thus, the specification contemplates that sequence variants of recombinant SSTRs, including truncation variants, are encompassed within the term "recombinant somatostatin receptor."

Therefore, in view of the above, the written description requirement for the claims has been met because the specification would reasonably convey to one of ordinary skill in the art that the inventors had possession of the claimed invention. Applicant therefore respectfully requests that this rejection should be withdrawn.

E. The Claim Rejections Under 35 U.S.C. §112, Second Paragraph, are Overcome

Claims 64 and 81-83 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, the Action asserts without a sequence of reference, claims that state that amino acids C-terminal to amino acid 314 of the SSTR2A protein are vague and indefinite. Applicant respectfully traverses and respond as follows.

As discussed above, SSTR sequences, including the SSTR2A sequence, are well-known in the art. Applicant is not required to recite in the specification sequences that are known in the art. See *Capon v. Eshhar v. Dudas*, 418 F.3d 1349, discussed above.

The sequences of SSTR receptors are well-known in the art. In particular, "[g]ene sequences encoding human, rat, and, in some cases mouse somatostatin receptor (SSTR) subtypes 1, 2, 2b, 3, 4, and 5 have been published in the literature." Citing Bruns *et al.*, Ann. NY Acad. Sci, 733, 138-146, 1994, and references cited therein. Further, accession numbers for exemplary mRNAs encoding these receptors can be found in para [0081] of the specification.

Regarding SSTR2A, and type of SSTR receptor, Applicant points out that the specification includes substantial information regarding this sequence. For example, information regarding the cloning of this sequence can be found in the Examples in paras [0058]-[0074] of the specification. Information regarding the structure and function of SSTR2A receptors is

discussed in the specification. See, *e.g.*, para. [0065], citing Koenig, *et al.*, Biochem. J. 336:291-298 and Roth *et al.*, DNA and Cell Biology 16:111-119, 1997.

Regarding the amino acid sequence of human SSTR2, attached herein as Exhibit 1 is a copy of the sequence information obtained from three different citations (accession numbers AAH95495, AAH19610, and NM_001050.2). Truncation at amino acid 314 of each of these sequences shows that the same C-terminal sequences would be removed. Further, attached as Exhibit 2 is a copy of amino acid sequence information pertaining to human SSTR2A (AAF42802). Truncation of this sequence would result in removal of the same C-terminal amino acid sequences that are removed in truncation of the SSTR2 receptor.

"The test for definiteness is whether one skilled in the art would understand the bounds of the claim when read in light of the specification." *Miles Laboratories, Inc. v. Shandon, Inc.*, 997 F.2d 870, 875, 27 USPQ2d 1123, 1126 (Fed. Cir. 1993). Claims are in compliance with 35 U.S.C. §112, second paragraph, if "the claims, read in light of the specification, reasonably apprise those skilled in the art and are as precise as the subject matter permits." *Hybritech, Inc., v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94-95 (Fed. Cir. 1987).

In view of the above, one of ordinary skill in the art would be able to understand the bounds of what is encompassed by a truncation at amino acid 314 of SSTR2 or SSTR2A. Therefore, it is respectfully requested that this rejection should be WITHDRAWN.

F. Conclusion

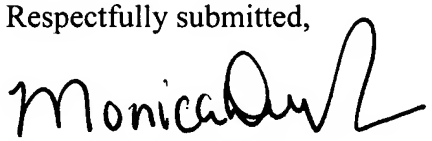
In view of the above, Applicant respectfully submits that each of the rejections in the Office Action have been overcome, and that all claims are in condition for allowance.

III. PETITION FOR EXTENSION OF TIME

Pursuant to 37 C.F.R. § 1.136(a), Applicant petitions for an extension of time of one month to and including April 17, 2006, in view of the Saturday, Sunday, Holiday rule, in which to respond to the Office Action dated December 15, 2006. Pursuant to 37 C.F.R. § 1.17, a check is enclosed, which is the process fee for a one-month extension of time. If the check is inadvertently omitted, or should any additional fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to the enclosed materials, or should an overpayment be included herein, the Commissioner is authorized to deduct or credit said fees from or to Fulbright & Jaworski Deposit Account No. 50-1212/UTSC:753US.

The Examiner is invited to contact the undersigned attorney at (512) 536-5639 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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Date: April 17, 2006